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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,481	03/10/2004	John G. Stark	5035.01US02	3292
62274	7590	02/03/2009	EXAMINER	
DARDI & ASSOCIATES, PLLC			COMSTOCK, DAVID C	
220 S. 6TH ST.				
SUITE 2000, U.S. BANK PLAZA			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55402			3733	
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			02/03/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/797,481	STARK, JOHN G.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DAVID COMSTOCK	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 November 2008.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 21-24 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-24 and 28-36 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 November 2008 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>30 DEC 2008</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-24 and 28-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The citations offered by Applicant do not appear to provide support for the claim language. Applicant should present arguments detailing how the wording in the specification applies to the different wording used in the claims, if a nexus of support is to be found.

Claims 21-24 and 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The meaning of the term "ligamentotaxis" is unclear, as set forth in this action under the heading "Response to Arguments."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-23, 28, 29, 32, 33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by the Cain (U.S. Patent Number 5,334,205).

Cain discloses a method for immobilizing a patient's sacroiliac joint comprising inserting an immobilization/fusion element into the opening of the sacroiliac joint between the ilium, 56, and the sacrum, 54, through a cannula, e.g. 68, that is placed through an incision formed in the patient, drilling a region at the sacroiliac joint through the cannula, and placing a guide pin, e.g. 70, through the cannula, further including a trocar, e.g. 66, self-tapping screws, e.g. 58, and a drilling guide (see figures 3-5 and column 4, lines 4-48).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Chang et al. (U.S. Patent Publication Number 20020099288)

Cain discloses the claimed method except for the use of real time imaging. Chang et al. discloses the use of real time imaging in order to guide the placement and orientation of an object (see paragraph 0013 and paragraph 0032). It would have been obvious to one skilled in the art at the time the invention was made to incorporate in the method of Cain the use of imaging in view of Chang et al., in order to guide the placement and orientation of the pin.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Bowman et al. (U.S. Patent Number 4,950,270).

Cain discloses the claimed invention except for the screw being associated with or coated with a biologically active agent. Bowman discloses a screw and teaches that the screw is constructed and/or coated with a biocompatible material and teaches the use of biocompatible material to allow for permanent or long term placement in association with cancellous bone and soft tissues and to promote osteointegration (see Column 3, lines 13-17). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cain with the screw being associated with or coated with a biologically active agent, in view of Bowman, in order to allow for permanent or long term emplacement in association with cancellous bone and soft tissues and to promote osteointegration.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Helland (4,488,542).

Cain discloses the claimed invention except for the immobilization/fusion element being an unthreaded pin. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the immobilization/fusion element without any threads, for example, to reduce cost or facilitate placement of the element in bone, since applicant has not disclosed that doing so solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an immobilization/fusion element for the joint. *In re Dailey and Eilers*, 149 USPQ 47 (1966). Moreover, bone pins and bone screws are very well-known functional equivalents in the art for providing fixation of bone, and either could be used by a person having ordinary skill in the art (e.g., an orthopedic surgeon) as desired and/or to accommodate individual patient conditions. For example, Helland teaches that internal bone fractures may be fastened by means such as screws, nails, pins, etc. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted a pin for a screw as the immobilization/fusion element, as desired and/or to best accommodate individual patient conditions, in view of Helland, as such would amount to nothing more than the substitution of functionally equivalent structures that are known in the art for treating bone.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cain (U.S. Patent Number 5,334,205) in view of Skiba (5,743,914).

Cain discloses the claimed method except for explicitly reciting that the immobilization/fusion element could have a central channel and be inserted over a guide pin. Again, although such a well-known and obvious feature should not even require any belaboring, it is noted that Skiba (for one example) shows a bone screw and teaches that it may be provided with a central channel and be inserted over a guide pin to "ensure optimal placement of the screw and, thus, proper mending of the bone structure." (col. 6, lines 39-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to likewise have provided the immobilization/fusion element of Cain with a central channel and to have inserted it over a guide pin, in view of the knowledge generally available to a person having ordinary skill in the art and numerous prior art references, including Skiba, in order to, for example, ensure optimal placement of the screw and proper mending of the bone structure.

### ***Response to Arguments***

Applicant's arguments filed 17 November 2008 have been fully considered, but they are not persuasive.

First, it is noted that various trademarks have been incorrectly used in Applicant's remarks ("power points" and "Wikipedia" (see page 6)). These terms should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary

nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Next, Examiner incorporates by reference the previous response to arguments, wherein it was explained how Cain can be seen as satisfying the claim language pertaining to the immobilization/fusion element being between the ilium and sacrum bones.

Regarding the amended claim language, it is noted that there are still at least two remaining problems with the amended claims. First, the meaning of the term “ligamentotaxis” has not been established. Applicant cites “the attached sheets from Wikipedia information” to present an alleged definition for the term (see Remarks, page 6). However, the only attachment presented to the Office was from WIKIANSWERS (WikiAnswers<sup>TM</sup>), a collaborative, user-supported question and answer service, not WIKIPEDIA, the ubiquitous collaborative online encyclopedia. As would be the case with a definition from WIKIPEDIA, the definition from WIKIANSWERS can in no way be relied upon because it is unclear who wrote the definition and whether the definition is even accurate. As the disclaimer on the page of the alleged definition states, anyone can write the answers and there is no guarantee of validity. Moreover, the disclaimer specifically elaborates that the information cannot be relied upon for medical advice (emphasis added in bold italics):

**No Guarantee of Validity**

*...Answers does not endorse, approve, or certify such information, nor does it guarantee the accuracy, completeness, efficacy, timeliness, or correct sequencing of such information. Information in the Services may or may not be current as of the date of your*

access, and Answers has no duty to update and maintain the information, reports, or statements on the Services. Additionally, the information in the Services may be changed periodically without prior notice. All content in the Services is provided "as is." Use of such information is voluntary, and ***reliance on it should only be undertaken after an independent review of its accuracy, completeness, efficacy,*** and timeliness. Additionally, please note that WikiAnswers is a community-based question-and-answer service using the "wiki" approach of developing answers that the community constantly improves. ***Answers allows ANYONE at any time to write and edit content in this service...***

**No Medical Advice**

The Services contain information on many medical topics; however ***there is absolutely no assurance that any information touching on medical matters is true, correct, or precise.***

Moreover, the definition does not appear to even apply to the present application because it deals with "retropulsed intraspinal bony fragments" and requires an application of "lordosis...forces." These elements are not found in the present application. Second, the claims set forth an intended reason for inserting an immobilization/fusion element (i.e. "to provide distracting forces resulting in ligamentotaxis *to drive apart the surfaces...*") (emphasis added in italics) but do not require the same through positively claimed steps (e.g., "distracting," "driving apart," etc.). As such, Cain still satisfies the claims.

Finally, Examiner does not agree with Applicant's characterization of the previous interview. Examiner did not indicate that the "application is probably allowable," as asserted by Applicant in the arguments filed 17 November 2008. Rather, Examiner and

Applicant discussed possible ways to amend the claims, and it was clearly stated that any allowability of the claims would depend on the particular language actually set forth in the amended claims, as well as on the results of an updated search. In any event, the application, as it presently stands is not allowable for the reasons set forth above.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's

supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/  
Examiner, Art Unit 3733

/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733